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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,784	08/18/2003	Ulrich Feige	A-527E	8073

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EXAMINER	
WESSENDORF, TERESA D	
ART UNIT	**PAPER NUMBER**
1639	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/645,784	FEIGE ET AL.	
	Examiner	Art Unit	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28,29,40,46-51 and 63-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28,29,40,46-51 and 63-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 28-29, 40, 46-51 and 63-71 are pending and under consideration in the application.

Withdrawn Objection and Rejection

In view of the amendment to the specification and applicants' arguments, the objection to the specification as set forth at page 4 of the last Office action is withdrawn. Also, the 35 USC 112, first paragraph rejection of the claims is withdrawn.

Specification

The abstract of the disclosure is objected to because it is not on a separate sheet. Note the amendment to the abstract made on 10/23/2006 was not on a separate sheet.

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph ***on a separate sheet*** within the range of **50 to 150 words**. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28-29, 40, 46-51 and 63-71, as amended, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claim 46 is unclear as to the step of preparing a compound "**incorporating** at least one …". It is unclear as to the step of incorporating the peptide into the compound. The peptide seems to be incorporated into several ways. Are the two incomplete steps done simultaneously i.e., after the peptide is selected from the phage display, is it formed into the compound of step b?

2. Claim 28 is confusing as it depends on the newly amended claim 46. Claim 46 recites a selected peptide, not a **gene** that encodes said peptide, especially for a multimer of 40 amino acids.

3. Claim 40 is confusing and unclear as it relates to step (a). Step (a) does not recite an Fc domain and relates to phage

display technique. The use of mutagenic primers recited in step b (i) and (ii) is unclear as it applies to the construct.

4. Claims 69-71 do not further limit claim 46 as the claimed limitation of a library as a "phage display library" is already recited in claim 46, as now amended.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Double Patenting

Claims 28-29, 40, 46-51 and 63-71, as amended, are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26-32, 34, 43-46 and 48-51 of copending Application No. ***10/653,048*** ('048 application) or 26-32, 34, 43-46 and 48-51 of copending Application No. ***10/651,723***('723 application) or 26-32, 34, 43-46 and 48-51 of copending Application No. ***09/563,286*** ***(***'286 application***)*** or 26-32, 34, 43-46 and 48-51 of copending Application No.***10/645***,761 ('761 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because each of the claims of the copending '048, '723, '286 and '761 recites the same broad process steps except employing different compounds distinguished one from the other by their functions. However, the functions of the peptides do not differentiate one compound from the other.

Furthermore, each of the copending applications also recites the same Fc containing compounds. The same process steps are used for each of the Fc-containing compounds.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 28-29, 40, 46-51 and 63-71, as amended, are rejected on the ground of nonstatutory double patenting over U. S. Patent No. 6,919,426('426) or U. S. Patent No. 6,660,843 ('843) since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: the instant method is fully disclosed at col.7, line 17 up to col. 8,line 28 of ht '426 patent. See the abstract of the '843 Patent.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Response to Arguments

Applicants argue that prosecution on the above applications has continued and in some applications will continue, such that the claims will not overlap. In particular, three of the applications have since been allowed and claim only compositions of matter. The claimed process already is not overlapping with that composition of matter applications, as it is not overlapping with the granted patent in this family (U.S. Pat. No. 6,660,843). Furthermore, applicants assert that the prosecution that led to the patent included an extensive restriction requirement that did not allow the current claims to be pursued therein.

In reply, even though some of the applications (not identified) have issued into patents however, each of the issued patents discloses the instant method. Furthermore, the allowed application that issued into a patent does not appear to claim the instant process of preparing a pharmacologically active compound. (Applicants are requested to submit a copy of the alleged extensive restriction requirement that restricted the present method from the parent issued Patent).

In the absence of a terminal disclaimer, the instant claimed method which recites similar process steps as the e.g., '286 application, the rejection is maintained.

[Applicants are requested to identify any other copending applications (or issued Patents) that have not been included above, to ascertain if a potential double patenting rejection has to be made. It appears that there are several applications ensuing from the parent application].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 28-29, 40, 46-51 and 63-71, as amended, are rejected under 35 U.S.C. 103(a) as being unpatentable over Chamow et al (TIBTECH) in view of Staten et al (WO 97/12978) and either applicants' disclosure of known prior art or Russell.

Chamow et al disclose at page 56, col. 1 (referring to de Sauvage) a technique of generating a fusion protein where the Fc regions of Ig is combined with a ligand c-MPl that recognizes a thrombopoietin receptor expressed in host cells. Table 1 at page 52 discloses the different immunoadhesin, inter alia,

thrombopoietin. Fig. 3 at page 55 shows the multimeric form of immunoadhesins. Chamow discloses at page 55 up to page 57 that immunoadhesins can be used as antagonists or agonists that block or mimic physiological molecular interactions. Immunoadhesins as disclosed by Chamow at page 567 is useful in studies designed to investigate the biological functions of new or novel receptors or ligands. Phage display expression libraries are suggested at page 50. Chamow does not disclose the use of the linker, (Gly)5. However, Staten et al disclose at page 33 linkers that may be composed of original peptide sequences that can be lengthened to be flexible and hydrophilic, example, (Gly)3Ser. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made prepare a compound using phage display since Chamow teaches said method or at least suggest said method. To include a linker in the fusion protein of Chamow would have been obvious (at times are optional) as linkers provide flexibility, especially those containing gly residues as taught by Staten.

Applicants at page 12, lines 9-15 states that "The compounds of this invention may be prepared by standard synthetic methods, recombinant DNA techniques, or any other methods of preparing peptides and fusion proteins….." Applicants continue at page 76, line 1 up to page 77, line 10

that "….the compounds of this invention largely may be made in transformed host cells using recombinant DNA techniques. To do so, a recombinant DNA molecule coding for the peptide is prepared. Methods of preparing such DNA molecules are well known in the art. For instance, sequences coding for the peptides could be excised from DNA using suitable restriction enzymes. Thus at the time of applicants' invention, phage display method is well-known method of making specific peptides.

Response to Arguments

Applicants state that the Staten reference (WO 97/12978) is cited in the Office Action only for certain linkers. It includes no teaching relevant to step (a) or step (b) of Claim 46. The Chamow et al, reference is a review article on immunoadhesins. By its own terms, the Chamow reference makes the Applicants' case for patentability. The authors' definition considers only natural proteins linked to Fc. Their extensive review shows that only natural protein-Fc fusions had been reported. The claimed process, in contrast, requires selection of peptides from a library, and such libraries can be formed by random mutagenesis. Chamow et al.'s review article, however, shows that those in the art had not considered combining peptide library selection and Fc fusion. The Office Action also seized upon the Applicants' non-controversial statements on use of techniques known in the

art, statements with which the Examiner apparently agrees. These statements support enablement and do not render the claimed process obvious. Although one may use known techniques to make them, the art simply did not suggest making the molecules defined by the structure shown in step (b) of Claim 46. The prior art further did not suggest using peptides selected by peptide phage display (step (a) of Claim 46) in molecules defined by the structure shown in step (b) of Claim 46. The Applicants, not the prior art, put together the claimed process.

In reply, applicants' arguments that the library is formed from random mutagenesis are not commensurate in scope with the claims. The claims do not recite for random mutagenesis. Be it as it may, it is immaterial as whether the peptide is obtained from phage library as there is nothing in the claims to preclude the natural protein of Chamow. As applicants stated above, phage display technique to obtain a peptide is a well-known technique at the time of applicants' invention. The statement made by applicants' in the disclosure, albeit to support an enablement rejection, is an acknowledgement as to the well-known phage display technique. See also the Russell reference. What is important is that the claimed method of preparing a pharmacologic agent by fusing it to a Fc is known in the art,

irrespective of the peptide preparation, especially since the claimed method does not define any peptide structure.

No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

T. D. Wessendorf
Primary Examiner
Art Unit 1639

Tdw
January 8, 2007